

**Remarks**

Claims 1-9, 11-14, and 26-34 are pending in the application.

With this Response, new claims 35-44 are added.

With the addition of claims 35-44, there are now ten additional claims in excess of twenty. The additional claims fee of \$520.00 is being charged to a credit card.

Claims 1-9, 11-14, and 26-44 remain in the application for consideration.

Support for the added claims 35-44 can be found in the specification as originally filed, for example at Figures 5, 5a, p. 9, lines 6-9, p. 13, lines 6-16.

Reconsideration and allowance of the claims as pending are respectfully requested.

**Claim Rejection - 35 USC § 103**

Claims 1-9, 11-14, and 26-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Salama (U.S. Patent No. 5,306,226; hereinafter referred to as “Salama”) in view of Kirsch et al. (U.S. Patent No. 6,461,367; hereinafter referred to as “Kirsch”).

Applicants traverse the rejection of claims 1-9, 11-14 and 26-34. For the reasons discussed below, the rejection is legally insufficient and should be withdrawn.

**The Salama reference**

The Salama reference describes a device used to drain a bladder (col. 2, line 18) including a urine tube having sidewalls, sidewall openings, and a balloon formed in part by the sidewalls that may be inflated (col. 2, lines 23-29) to correspond to the shape of the inner side walls of a bladder (col. 2, lines 40-43). An “anchoring collar means” frictionally engages the outer surface of the urine tube and is positioned against the outside of the body at the outer end of the urethra to hold the balloon in tight sealing contact with the bladder orifice and neck (col. 2, lines 35-38, 50-51 and col. 3, lines 18-22). The anchoring collar means can be moved lengthwise along a serrated surface of the urine tube (col. 2, lines 50-56). Serrations on the inside face of the anchoring collar means register with serrations on the outside of the urine tube and hold the anchoring collar means in place at a desired location. Urine is prevented from leaking around the urine tube by the seal that the balloon provides with the bladder neck (col. 3, lines 23-26).

The stated function of the Salama device and process is for urine control (col. 2, lines 18-22). The device is left in place in the body to perform that function.

### **The Kirsch reference**

The Kirsch reference describes a device that, in combination with “clips,” can be used to reconnect a urethra and a bladder after a radical retropubic prostatectomy (col. 1, lines 13-16). The embodiment referred to in the Office Action (according to the Office action, shown at Figs. 14, 17-18, but that is also shown at figures 12 and 13) is a “dual approximator” that is inserted in a patient transurethrally (col. 6, line 21). The dual approximator comprises an elongate cannula separable into two “units,” which are a “bladder everting unit” and a “urethra everting unit.” The bladder everting unit, during use, is extended distally and returned proximally to a position near the urethral everting unit (see e.g., column 7, lines 45-51; column 6, lines 26-34; and figures 12 and 13). Each everting unit includes a set of openings through which extend sets of bladder everting prongs and urethra tissue everting prongs (col. 6, lines 22-29).

To use the dual approximator in an anastomosis procedure, a surgeon inserts the device transurethrally until the bladder everting unit emerges from an opening caused by removal of a prostate (col. 7, lines 53-60). Next, the bladder everting unit is moved distally to create a gap between the bladder everting unit and the urethra everting unit (col. 7, lines 60-64). See figure 13. The bladder everting unit is then inserted into the bladder opening (col. 7, lines 64-65), and the everting prongs are extended to “contact and evert” bladder tissue (col. 7, line 67 - col. 8, line 3). The prongs of the urethra everting unit are extended to “evert” the end of the urethra (col. 8, lines 4-5). Next, the bladder and urethra everting units are moved closer relative to one another to bring the bladder tissue and urethra together (col. 8, lines 4-10). The surgeon then applies clips to hold the bladder tissue and urethra together (col. 8, lines 9-18). The “everting prongs” are not described as useful to hold tissue together for healing. To the contrary, the everting units and everting prongs, the entire dual approximator device, are removed from the urethra leaving only the clips in place to hold the tissues together (col. 8, lines 12-18).

**The Office Action fails to support the rejection because the “articulated reasoning” upon which the rejection is based is confusing, is not clear, and is not considered to be based on a “rational underpinning”**

The Office Action fails to support the rejection of claims 1-9, 11-14, and 26-34 because the rejection fails to provide a clear articulated reasoning based on some rational underpinning for the conclusion of obviousness.

M.P.E.P. § 2143.01(IV) provides:

A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some **articulated reasoning with some rational underpinning** to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

M.P.E.P. § 2143.01(IV) (emphasis added). Thus, to establish *prima facie* obviousness a rejection must provide “some articulated reasoning with some rational underpinning.” To include a “rational underpinning,” the “articulated reasoning” should be clear on its face and not confusing and should be technically sound.

The Office Action asserts:

*[i]t would have been obvious . . . to replace the tissue approximating structure or means of Salama with one comprising multiple opposing tines at the distal end of a catheter body, as taught by Kirsch et al. in order to facilitate the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines, making the process more efficient and simple to use.* (Office Action, pp. 3-4) (emphasis added).

The proffered reasoning is unclear and confusing to the Applicants. The language “making the process more efficient and simple to use” does not make clear which of more than one possible “process” is being referenced, e.g., the Salama process or the Kirsch process. Because which “process” referred to is unclear, we consider both possible alternate meaning, the Salama process and the Kirsch process.

Regardless of which “process” is referred to, the articulated reasoning is ultimately unpersuasive. When the features of the Kirsch device are combined with the Salama device, as proposed, with the teachings of these references being properly considered in their entireties and as a whole, neither the Salama process nor the Kirsch process becomes “more efficient” or “simple to use” relative to the respective original process. Consequently, the stated reasoning is not technically sound, is not persuasive, and does not include a “rational underpinning” to support the rejection.

**If the “process” referred to is the Salama process of “controlling urine flow” the articulated reasoning is unpersuasive**

The Salama “process” is for “urinary control” or “controlling the flow of urine.” Salama provides that:

*An anchoring collar means 36 . . . frictionally engages the outer surface of the urine tube 12 [and is positioned against the outside of the body at the outer end of the urethra] to hold the walls of the balloon 26 in tight sealing contact with the bladder orifice and neck.*

(Salama, col. 2, lines 35-40, 50-51).

The Salama device for performing this function is relatively simple and includes a balloon catheter with a simple collar means located and positionable along the external portion of the device. The device is simple and the method merely requires placing the device in the patient, adjusting the placement, and leaving the device internal to the patient to allow drainage of urine.

The Kirsch device is far more complex, as is the Kirsch process. The Kirsch device includes “everting structures” that function at locations internal to the patient (i.e., contact internal tissue) to “evert” bladder and urethral tissues after a prostatectomy. The “everting” structures are substantially more complex than the simple external “collar means” of Salama. As a result, neither efficiency nor simplicity of a urinary control process would have been a reason to replace the simple collar of Salama with the more complex “everting” structure of Kirsch.

Moreover, there is no reason to believe that the Kirsch “everting” structure would be capable of performing the function of the Salama “anchoring collar means” (even with its relatively complicated mode of “everting” tissue internal to the patient). There is no reason to

believe that the “everting” structure of Kirsch is useful to “hold the balloon 26 in tight sealing contact with the bladder orifice and neck.” The Kirsch structure, instead, is used to “evert” tissues, not to cause a balloon to create a seal within a bladder. One of skill would have had no reason to substitute the relatively simple “collar means” of Salama with the more complicated “everting” structure of Kirsch (i.e., two moveable everting units including prongs, and clips to hold tissue in place), to perform the Salama process of urine control.

If the “process” referred to in Office Action is the Salama process of “controlling urine flow,” the reasoning in the Office Action is unpersuasive. Replacing the simple “anchoring collar means” of the Salama reference with the complex structure of Kirsch would not make the process of urinary control of Salama more efficient or simple. Accordingly, the proffered articulated reasoning for the rejection is not persuasive, is not considered to be a “rational underpinning” supportive of the rejection, and the rejection should be withdrawn.

**If the “process” referred to is the Kirsch process of “approximation of tissue portions,” the articulated reasoning is also not a “rational underpinning”**

The “process” of the Kirsch reference involves approximation of tissue in an anastomosis procedure. The procedure is carried out using a complex device referred to as a “dual approximator” to “evert” tissue, in combination with “clips” required to hold tissue together. After the “clips” are placed to hold tissue together the dual approximator is removed from the patient.

The process of using the Kirsch dual approximator device includes inserting the device (in the configuration illustrated at figure 12) so the bladder everting unit and the urethra everting unit are located near the respective bladder and urethral tissues, which are severed. The bladder everting unit is then extended distally away from the urethra everting unit (to achieve the configuration of figure 13), and into the bladder opening. Next, bladder everting prongs are extended to contact and “evert” bladder tissue. Everting prongs also “evert” the end of the urethra. The bladder everting unit is then retracted toward the urethra everting unit, to bring the bladder and urethral tissues together. Next, clips are applied to hold the tissue together and the device is removed. The clips are not optional, e.g., because the dual approximator is removed; the “everting prongs” are not used to hold tissue together for healing.

Applicants emphasize that this method -- including the requirement of a “dual approximator” with a bladder everting unit, and clips required to hold tissue together -- is the only method of tissue approximation described by the Kirsch reference. The Kirsch method is not shown to be capable of simplification, e.g., by being performed without the required clips, or by using the “everting prongs” to hold tissue during healing. As an unambiguous result, a device that combines the structure of Kirsch -- taken as a whole, as is required -- with the balloon catheter of Salama, does not produce a device that would allow for an anastomosis procedure to be performed with reduced complexity or simplicity, as asserted. Adding the “everting” structures of the Kirsch device to the Salama balloon catheter would not eliminate any steps in the process of tissue approximation described by Kirsch. The process would still require the everting of tissues as described, using a “bladder everting unit” that extends and retracts along the length of the device, as well as placement of clips to hold the tissues together. Plainly, the assertion that the cited combination of references would result in a Kirsch anastomosis process that is either more simple or efficient is inconsistent with the technical content of the references, which does not allow for “simplification” of the Kirsch reference, but requires, e.g., the use of both a “dual approximator,” and “clips” to hold tissue together.

Generally, the patent laws require that when used to assess obviousness of later claims, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). When applied to the cited references, all of the features of the prior art subject matter must be considered and not disregarded. The device and design of the Kirsch reference cannot, when taken as a whole, be added to the Salama device for the reason of improving efficiency or simplicity of a method of using the device. Taken as a whole, the structure of Kirsch, added to the Salama device, would result in a process that would be no more simple or effective than the original Salama or Kirsch process.

Further, as opposed to taking the teaching of a reference as a whole, it is impermissible in an obviousness analysis to pick and choose from prior art information, only features that relate to an applicant’s claims. Any use of an Applicant’s own specification and claims as a “template,” followed by selection of only relevant (i.e., claimed) features from prior art information, to

reconstruct a claimed invention, is impermissible hindsight. See *In re Gorman*, 933 F.2d 982, 987, 18 U.S.P.Q.2d (BNA) 1885, 1888 (Fed. Cir. 1991); M.P.E.P. § 2143.01.

On the present facts, for example, the Kirsch reference does not include any teaching or suggestion that the “everting prongs” may be useful to hold tissue together for healing while the Kirsch device remains in a patient for a healing period, or that the clips would be unnecessary (e.g., a simplified or more efficient anastomosis method). To the contrary, the Kirsch reference teaches exclusively to hold tissue together using the described clips (not everting prongs, as would be more simple), and to remove the “dual approximator” device. A rejection cannot consider only the “everting prongs” while ignoring the required clips, to conclude that one of skill would have arrived at a simplified or more efficient device or process, such as one that does not use the clips. Simply put, neither that method nor a device useful to perform that method is taught or suggested by the cited references either separately or in combination.

**New claims 35-44**

The Response adds new claims 35-44. Features of these claims are believed to be neither taught nor suggested by the combined Salama and Kirsch references. One example of an added feature is that certain features of claimed devices such as a balloon or tissue approximating structure are said to be fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body. These features are neither taught nor suggested by either the Salama or Kirsch references. The anchoring collar means of Salama is not fixed but can be moved relative to both the distal and proximal ends of the catheter body. The everting prongs of the cited Kirsch devices (e.g., at figure 14) are moveable relative to a proximal or a distal end of the “dual approximator.”

**Conclusion**

In view of the present remarks, Applicants submit that the outstanding rejection has been either overcome or should otherwise be withdrawn. Reconsideration of the claims, and allowance of the new and pending claims, are respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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